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10/520,221

07/27/2005

Christopher Robin Lowe

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO Box 142950  
GAINESVILLE, FL 32614

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

09/08/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

|                              |  |                                    |  |
|------------------------------|--|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/520,221     | <b>Applicant(s)</b><br>LOWE ET AL. |  |
|                              | <b>Examiner</b><br>Kailash C. Srivastava | <b>Art Unit</b><br>1657            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 19 June 2009 after a Final action mailed 19 March 2009. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 19 March 2009 has been withdrawn pursuant to 37 C.F.R. §1.114. Accordingly, an R.C.E. has been established and the action on R.C.E. follows.

2. The remarks and amendment filed 19 March 2009 are acknowledged and entered.

## Withdrawn Rejections

3. In consideration of amendments and remarks filed 19 June 2009; following rejections in Office Action mailed 19 March 2009 are hereby withdrawn:

- Obviousness rejection to Claims 1-6 and 8-13 under 35 U.S.C. §103(a) as being unpatentable over Lowe et al. (o 95126499).

## Claims Status

4. Claims 6-7, 9 and 14 are cancelled.
5. Claims 1, 5, 8 and 10-11 have currently been amended.
6. Claims 1-5, 8 and 10-13 are pending and are examined on merits.

## *Claim Rejections - 35 U.S.C. § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

8. Claim 2 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- In Claim 2, the phrase “wherein the cell is immobilized on a magnetic particle” lacks sufficient antecedent basis because in Claim 1 from which Claim 2 depends the limitation is “immobilizing the cell on an antibody”. Appropriate correction/ explanation is required.

### ***Claim Rejections - 35 U.S.C. §102/§103***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

10. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

12. Claims 1-5 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, Number 9, Pages 3474-3476).

Claims 1-5 are drawn to a method to identify a cell or metabolites thereof, wherein the cell is immobilized to an antibody and is also in a device containing a sensor, a growth medium addition step, wherein said sensor is holographic, sensitive to a product of cell's growth and detects changes in an optical characteristic of said sensor.

Regarding Claims 1-5, Bruno et al., teach detection of anthrax spores in soil suspensions through an immunomagnetic electrochemiluminescence method, wherein anthrax spores in the range of 0-10<sup>6</sup>

were detected. Bruno et al., further teach immobilizing the spores to a spore-specific antibody, wherein said antibody is attached to biotinylated Dynal magnetic beads. After addition of target samples to said beads, the sample+ beads mixture was treated with ruthenium-labeled Gt reporter antiserum, the samples were analyzed on an ORIGEN analyzer to detect the photon counts Abstract; Page 3474, Column , Lines 18-35). Bruno et al., additionally teach detection of said spores in a soil sample. Note since the spore sample also contained soil suspension, the sample was added with a growth medium because soil extract/suspension is an art-known microbiological culture medium. Furthermore, the spore is a product of cellular metabolism because spore is produced by the vegetative cell to sustain the unsuitable environmental/culture conditions for cell viability.

Therefore, the reference is deemed to anticipate the cited claims.

However, even if the reference and the claimed method are not one and the same and there is, in fact, no anticipation, the reference method would, nevertheless, have rendered the claimed method obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference teaches same materials and same steps except for the specific concentrations of the materials. The only difference between the reference method and the instantly claimed invention resides in the concentrations of spores or spore-contaminated sample. Nevertheless, the reference method (i.e., Bruno et al.) teaches a range of spores encompassing the same microorganisms (e.g., *Bacillus anthracis* and *Bacillus thuringiensis*). Additionally, if there is any guidance in the reference regarding the concentration range of a material as is presented in at Page 3474, Column 2, Line 24 from Bruno et al.; the adjustment of particular conventional working equivalents (e.g., concentration) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan for which the Examiner –cited reference has provided some guidance.

Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear and convincing evidence to the contrary.

From the teachings of the reference cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 U.S.C. §103***

13. Claims 1-5, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being obvious over Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of Bacillus anthracis Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, No. 9, Pages 3474-3476) in view of Walt et al (US 6,377,721 B I), and Weimer et al (US 6,399,317, issued 4 June 2002).

Claims 1-5, 8 and 10-13 are drawn to a method to identify a cell or metabolites thereof, wherein the cell is immobilized to an antibody and is also in a device containing a sensor, a growth medium addition step, wherein said sensor is holographic, sensitive to a product of cell's growth and detects changes in an optical characteristic of said sensor. Claims also describe a device to detect cells, wherein said device comprises a series of chambers, a holographic sensor, an antibody, and a growth medium and an inlet for the sample. The antibody is immobilized on a wall of a chamber and said antibody immobilized on a magnetic particle

Regarding Claims 1-5, 8 and 10-13, the teachings of Bruno et al are discussed above and applied as before. Bruno et al., however, are silent regarding elaborating the device and details thereof. E.g., Bruno et al are silent about a device suitable for immobilizing a cell that also contains a sensor and a growth medium and further comprises a series of chambers. The sensor is a holographic detector.

Walt et al teach multiple chambers in a single device (see Abstract for example) and further teach that the cells can be immobilized by immunophilic and magnetic means (see column 12, lines 55-64, for example), and that cell metabolism can be monitored by provision of a fluorescent metabolite, that fluorophores responsive to the metabolite can be activated by excitation light, and resulting fluorescence can be detected by fiber optics (see col. 15, lines 48-54, for example). Please note, Walt et al., are intrinsically describe a holographic sensor because the metabolism of cells immobilized by immunophilic and magnetic means is being signaled through fluorescence manifesting the changes in the fluorescence, i.e., an optical characteristic.

Weimer et al teach a device for detecting bacteria. The device contains beads which are coated with an antibody specific for a type of bacteria; these beads can be magnetic. A sample suspected of

containing bacteria is added through an inlet port, and allowed to flow through a chamber containing the beads. The beads then selectively accumulate bacteria from the liquid sample (see col. 3 line 40 to col. 4 line 19; see col. 6 lines 13-21, as examples). The bacteria can also be subsequently washed while bound to the magnetic beads by addition of a wash buffer (see Example 13, for example). Weimer et al., also teach that bacterial spores can be used to generate antibodies in mice. These antibodies can also be attached to beads, and will effectively capture spores in the chamber discussed above (see Examples 2, 3; and 13).

A person of ordinary skill in the art at the time the invention was made would have been motivated to detect bacteria by trapping them on beads with antibodies and detect their presence by means of a holographic sensor because Bruno et al., teach that bacteria can be trapped on magnetic beads by means of antibodies and that they can subsequently be cultured in liquid media, Walt et al., teach a biosensor in which immobilized cells are interrogated with a light source and optically measured and Weimer et al teach that cells attached to beads can be washed in a buffer solution.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide a device in which one can capture bacteria through antibody-antigen reaction on immunomagnetic beads coated with anti bodies to which bacteria are immobilized, provide them a growth medium, and observe their metabolism via optical interrogation with a holographic sensor

From the teachings of the reference cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

14. For the aforementioned reasons, no Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/  
Examiner, Art Unit 1657

Kailash C. Srivastava  
Patent Examiner  
Art Unit 1657  
(571) 272-0923

31 August 2009  
/David M. Naff/  
Primary Examiner, Art Unit 1657